REMARKS

Claims 1-27 remain pending in the application. Amendments have been made to improve their readability and technical accuracy. No substantive changes have been made.

The claims were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for referring to "montelukast." The Office Action described this as being a "common name" for a chemical that can change over time.

Montelukast is the adopted name that is given to a drug compound, in place of the rather cumbersome chemical name. The name was coined by the United States Adopted Name ("USAN") Council, a joint effort of the American Medical Association, the U.S. Pharmacopeial Convention, Inc., and the American Pharmacists Association. Typically, a USAN name is accepted by the U.S. Food and Drug Administration as the official name for the active ingredient (in accordance with 21 C.F.R. § 299.4), and its use in connection with sales of all branded and generic pharmaceutical products containing that active ingredient is mandatory. See the attached printout from the electronic version of the FDA's Orange Book for "montelukast," showing that the currently sold product contains the active ingredient "montelukast sodium," and that product has the proprietary name "SINGULAIR." Also see the attached first page of the current prescribing information for SINGULAIR®, showing that the film-coated tablet form of the product contains 10.4 mg of montelukast sodium, equivalent to 10 mg of montelukast.

Applicants submit that the adopted name "montelukast" will not be applied to a different compound, but rather is a fixed name in the United States for the specific drug compound. Accordingly, this rejection should be withdrawn.

The claims also were rejected under 35 U.S.C. § 112, second paragraph, as being ambiguous due to inclusion of compound names that did not appear to be proper. Applicants have now amended the claims to replace those names with their corresponding structural formulas from the reaction scheme on page 6 of the specification. Accordingly, withdrawal of this rejection is requested.

SUMMARY

Applicants submit that the rejections have been overcome, and that the amended claims are in condition for allowance. An early notification of their allowability is requested. However, if any minor matters remain to be resolved before disposition of the application, please contact the undersigned attorney to arrange for a telephonic or personal interview to discuss those matters.

Respectfully submitted,

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February 10, 2006

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Active Ingredient Search Results from "OB_Rx" table for query on "montelukast."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
021409		Yes	MONTELUKAST SODIUM	GRANULE; ORAL	EQ 4MG BASE/PACKET	SINGULAIR	MERCK
020830		No	MONTELUKAST SODIUM	TABLET, CHEWABLE; ORAL	EQ 4MG BASE	SINGULAIR	MERCK
020830		Yes	MONTELUKAST SODIUM	TABLET, CHEWABLE; ORAL	EQ 5MG BASE	SINGULAIR	MERCK
020829		Yes	MONTELUKAST SODIUM	TABLET; ORAL	EQ 10MG BASE	SINGULAIR	MERCK

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through December, 2005
Patent and Generic Drug Product Data Last Updated: February 09, 2006

MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

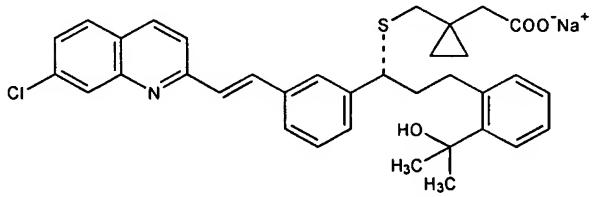
SINGULAIR®
(MONTELUKAST SODIUM)
TABLETS, CHEWABLE TABLETS, AND Oral Granules

DESCRIPTION

Montelukast sodium, the active ingredient in SINGULAIR*, is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene $CysLT_1$ receptor.

Montelukast sodium is described chemically as [*R*-(*E*)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropaneacetic acid, monosodium salt.

The empirical formula is $C_{35}H_{35}ClNNaO_3S$, and its molecular weight is 608.18. The structural formula is:



Montelukast sodium is a hygroscopic, optically active, white to off-white powder. Montelukast sodium is freely soluble in ethanol, methanol, and water and practically insoluble in acetonitrile.

Each 10-mg film-coated SINGULAIR tablet contains 10.4 mg montelukast sodium, which is equivalent to 10 mg of montelukast, and the following inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The film coating consists of: hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, red ferric oxide, yellow ferric oxide, and carnauba wax.

Each 4-mg and 5-mg chewable SINGULAIR tablet contains 4.2 and 5.2 mg montelukast sodium, respectively, which are equivalent to 4 and 5 mg of montelukast, respectively. Both chewable tablets contain the following inactive ingredients: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, red ferric oxide, croscarmellose sodium, cherry flavor, aspartame, and magnesium stearate.

Each packet of SINGULAIR 4-mg oral granules contains 4.2 mg montelukast sodium, which is equivalent to 4 mg of montelukast. The oral granule formulation contains the following inactive ingredients: mannitol, hydroxypropyl cellulose, and magnesium stearate.

CLINICAL PHARMACOLOGY

Mechanism of Action

The cysteinyl leukotrienes (LTC_4, LTD_4, LTE_4) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 ($CysLT_1$) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis. In asthma, leukotriene-mediated effects include airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process. In allergic rhinitis, CysLTs are released from the nasal mucosa after allergen exposure during both early- and late-phase reactions and are associated with symptoms of allergic rhinitis. Intranasal challenge with CysLTs has been shown to increase nasal airway resistance and symptoms of nasal obstruction. SINGULAIR has not been assessed in intranasal challenge studies. The clinical relevance of intranasal challenge studies is unknown.

* Registered trademark of MERCK & CO., Inc.